

## MAPS Prepares to Launch **MDMA**/PTSD Study in Israel



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On Thursday, August 3rd, in the midst of war, about 5 grams of MDMA arrived in Israel for MAPS' MDMA/PTSD study, imported into Israel from Switzerland. The MAPS-sponsored MDMA/PTSD pilot study is being directed by Moshe Kotler, M.D., with Rael Strous, M.D., and Rakefet Rodrigez, M.D., working as the male/female co-therapist team. This study has full government approval and will be initiated this fall.

At the time of this writing, Dr. Rodrigez is planning to take a break from the therapy work she is doing in the north of Israel with traumatized civilians and soldiers to join MAPS at Burning Man this August.

While joining us to celebrate MAPS' 20th anniversary, she will work at Sanctuary, where we assist the Rangers to care for people going through difficult emotional experiences, some psychedelic-related and some not. The Sanctuary project at Burning Man serves as a training program for MAPS' psychedelic therapists, a rare opportunity for researchers to spend time working alongside each other with people who are in a psychedelic-induced state.

Last May, both Israeli co-therapists traveled to the U.S. to observe a treatment session and receive training from Michael Mithoefer, M.D., and his wife Annie in Charleston, South Carolina. This visit not only informed the Israeli doctors about MAPS' therapeutic protocol, but also helped MAPS clarify and develop a standardized protocol as we prepare for larger multi-site studies with MDMA. As MAPS research liaison, I also had the pleasure of attending this very important meeting and I must say that Dr. Strous and Dr. Rodrigez make a very dynamic co-therapist team.

The Israeli study will feature supplemental dosing halfway through each of the MDMA-assisted psychotherapy

sessions, and will use an active placebo of low-dose MDMA. This will make it more difficult for the therapist and subject to be able to tell whether the subject received an active dose of MDMA or not, increasing the success of the double-blind measure. In this study, the researchers will also collect long-term follow-up data for one year after the second experimental session. The study in Israel also tests the efficacy of using slightly less staff time, since only one therapist is present during some of the non-drug therapy sessions, rather than both therapists. Both therapists are present during all of the experimental sessions where MDMA is administered, as well as during some of the non-drug therapy sessions.

This study, although conducted in Israel, will be submitted to FDA under MAPS' Investigational New Drug (IND) application for MDMA in the treatment of PTSD and therefore fits into MAPS' mission of developing MDMA as a prescription medicine approved by both the FDA and the European Medicines Agency. With government-approved research projects on three continents, MAPS is truly becoming a global organization!•